

Subject Case Report Forms

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the
Case Report Forms.

Medication name _____ ①

Indication _____ ②

Route

Oral	<input type="checkbox"/>	③
Intramuscular	<input type="checkbox"/>	
Intravenous	<input type="checkbox"/>	
Topical	<input type="checkbox"/>	
Inhalation	<input type="checkbox"/>	
Vaginal	<input type="checkbox"/>	
Rectal	<input type="checkbox"/>	
Subcutaneous	<input type="checkbox"/>	
Subdermal	<input type="checkbox"/>	
Sublingual	<input type="checkbox"/>	
Intrauterine	<input type="checkbox"/>	
Nasal	<input type="checkbox"/>	
Intraocular	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

If "Other", specify: _____ ④

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Concomitant Medications

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	CMTRT	\$200	Concomitant Medication Name			CMTRT
②	CMINDC	\$100	Concomitant Meds Indication			CMINDC
③	CMROUTE	\$5	Concomitant Meds Route of Administration		PO = Oral IM = Intramuscular IV = Intravenous TOP = Topical IHL = Inhalation VAG = Vaginal REC = Rectal SC = Subcutaneous SD = Subdermal SL = Sublingual IU = Intrauterine IHN = Nasal IOC = Intraocular OTHER = Other	CMROUTE
④	CMROUTEOSP	\$200	Concomitant Meds Route of Administration Other Specify			CMROUTEOSP

Did the participant experience any COVID-19 symptoms?

Yes ☐ 1
No ☐

If "No", end of form.

What was the date of onset of symptoms?

3

Total duration of acute symptoms

Fixed Unit: # days 4

During the illness, did the participant experience any of the following?

Fever

Yes ☐ 6

If "No" or "Unknown", go to Dyspnea with exertion

No ☐
Unknown ☐

Duration of symptom

Fixed Unit: # days 7

Maximum temperature

Fixed Unit: C 8

Respiratory/Cardiac

Dyspnea with exertion

Yes ☐ 10

If "No" or "Unknown", go to Dyspnea at rest

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 11
No ☐

Duration of symptom Fixed Unit: # days **12**

Dyspnea at rest Yes ☐ **13**
If "No" or "Unknown", go to Cough No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **14**
No ☐

Duration of symptom Fixed Unit: # days **15**

Cough Yes ☐ **16**
If "No" or "Unknown", go to Hemoptysis No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **17**
No ☐

Duration of symptom Fixed Unit: # days **18**

Hemoptysis Yes ☐ **19**
If "No" or "Unknown", go to Sputum production No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **20**
No ☐

Duration of symptom Fixed Unit: # days **21**

Sputum production Yes ☐ **22**
If "No" or "Unknown", go to Chest pain No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **23**
No ☐

Duration of symptom Fixed Unit: # days **24**

Chest pain Yes ☐ **25**
If "No" or "Unknown", go to Unable to sleep lying down No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **26**
No ☐

Duration of symptom Fixed Unit: # days **27**

Unable to sleep lying down Yes ☐ **28**
If "No" or "Unknown", go to Rhinorrhea/nasal congestion No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution? Yes ☐ **29**
No ☐

Duration of symptom

Fixed Unit: # days

30

HEENT

Rhinorrhea/nasal congestion

Yes ☐

32

If "No" or "Unknown", go to Sore throat

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐

33

No ☐

Duration of symptom

Fixed Unit: # days

34

Sore throat

Yes ☐

35

If "No" or "Unknown", go to Anosmia (loss of smell)

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐

36

No ☐

Duration of symptom

Fixed Unit: # days

37

Anosmia (loss of smell)

Yes ☐

38

If "No" or "Unknown", go to Ageusia (loss of taste)

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐

39

No ☐

Duration of symptom

Fixed Unit: # days **40**

Ageusia (loss of taste)

Yes ☐ **41**

If "No" or "Unknown", go to Anorexia

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ **42**

No ☐

Duration of symptom

Fixed Unit: # days **43**

Gastrointestinal

Anorexia

Yes ☐ **45**

If "No" or "Unknown", go to Nausea or vomiting

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ **46**

No ☐

Duration of symptom

Fixed Unit: # days **47**

Nausea or vomiting

Yes ☐ **48**

If "No" or "Unknown", go to Diarrhea

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 49
No ☐

Duration of symptom

Fixed Unit: # days 50

Diarrhea

Yes ☐ 51

If "No" or "Unknown", go to Abdominal pain

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 52
No ☐

Duration of symptom

Fixed Unit: # days 53

Abdominal pain

Yes ☐ 54

If "No" or "Unknown", go to Fatigue

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 55
No ☐

Duration of symptom

Fixed Unit: # days 56

General

Fatigue

Yes ☐ 58

If "No" or "Unknown", go to Myalgia

No ☐

Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ **59**
No ☐

Duration of symptom

Fixed Unit: # days **60**

Myalgia

Yes ☐ **61**

If "No" or "Unknown", go to Headache

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ **62**
No ☐

Duration of symptom

Fixed Unit: # days **63**

Headache

Yes ☐ **64**

If "No" or "Unknown", go to Confusion/mental status changes

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ **65**
No ☐

Duration of symptom

Fixed Unit: # days **66**

Confusion/mental status changes

Yes ☐ **67**

If "No" or "Unknown", go to Chills

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 68
No ☐

Duration of symptom

Fixed Unit: # days 69

Chills

Yes ☐ 70

If "No" or "Unknown", go to New skin findings attributable to COVID-19

No ☐
Unknown ☐

Does symptom persist after COVID-19 resolution?

Yes ☐ 71
No ☐

Duration of symptom

Fixed Unit: # days 72

Dermatological

New skin findings attributable to COVID-19

Yes ☐ 74

If "No", go to Other

No ☐
Unknown ☐

Specify (max 200 characters):

75

Does symptom persist after COVID-19 resolution?

Yes ☐ 76
No ☐

Duration of symptom Fixed Unit: # days **77**

Other

Other COVID-19 symptom Yes ☐ **79**
If "Yes", specify up to 3 symptoms below. No ☐
If "No", end of form.

Specify (max 200 characters): **80**

Does symptom persist after COVID-19 resolution? Yes ☐ **81**
No ☐

Duration of symptom Fixed Unit: # days **82**

Specify (max 200 characters): **83**

Does symptom persist after COVID-19 resolution? Yes ☐ **84**
No ☐

Duration of symptom Fixed Unit: # days **85**

Specify (max 200 characters): **86**

Does symptom persist after COVID-19 resolution? Yes ☐ **87**
No ☐

Duration of symptom	Fixed Unit: # days

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	MHCVYN	\$1	Any COVID-19 Symptoms		Y = Yes N = No	MHCVYN
3	MHSDAT	dd- MMM yyyy	Symptom Onset Date			MHSDAT
4	MHDURTOT	3	Acute Symptom Duration			MHDURTOT
6	FEVER_MHYN	\$1	Fever Occurrence		Y = Yes N = No U = Unknown	FEVER_MHYN
7	FEVER_MHDUR	2	Fever Duration			FEVER_MHDUR
8	FEVER_VSORRES	3.1+	Maximum Temperature			FEVER_VSORRES
10	DYSPN_MHYN	\$1	Dyspnea With Exertion Occurrence		Y = Yes N = No U = Unknown	DYSPN_MHYN
11	DYSPN_MHSTAT	\$1	Dyspnea With Exertion Persist		Y = Yes N = No	DYSPN_MHSTAT
12	DYSPN_MHDUR	2	Dyspnea With Exertion Duration			DYSPN_MHDUR
13	DYREST_MHYN	\$1	Dyspnea At Rest Occurrence		Y = Yes N = No U = Unknown	DYREST_MHYN

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
14	DYREST_MHST AT	\$1	Dyspnea At Rest Persist		Y = Yes N = No	DYREST_MHST AT
15	DYREST_MHD UR	2	Dyspnea At Rest Duration			DYREST_MHD UR
16	COUGH_MHYN	\$1	Cough Occurrence		Y = Yes N = No U = Unknown	COUGH_MHYN
17	COUGH_MHST AT	\$1	Cough Persist		Y = Yes N = No	COUGH_MHST AT
18	COUGH_MH DU R	2	Cough Duration			COUGH_MH DU R
19	HEMOP_MHYN	\$1	Hemoptysis Occurrence		Y = Yes N = No U = Unknown	HEMOP_MHYN
20	HEMOP_MHST AT	\$1	Hemoptysis Persist		Y = Yes N = No	HEMOP_MHST AT
21	HEMOP_MH DU R	2	Hemoptysis Duration			HEMOP_MH DU R
22	SPUTUM_MHY N	\$1	Sputum Occurrence		Y = Yes N = No U = Unknown	SPUTUM_MHY N
23	SPUTUM_MHS TAT	\$1	Sputum Persist		Y = Yes N = No	SPUTUM_MHS TAT

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
24	SPUTUM_MHD UR	2	Sputum Duration			SPUTUM_MHD UR
25	CHEST_MHYN	\$1	Chest Pain Occurrence		Y = Yes N = No U = Unknown	CHEST_MHYN
26	CHEST_MHSTA T	\$1	Chest Pain Persist		Y = Yes N = No	CHEST_MHSTA T
27	CHEST_MH DU R	2	Chest Pain Duration			CHEST_MH DU R
28	LYDOWN_MHY N	\$1	Sleep Lying Down Occurrence		Y = Yes N = No U = Unknown	LYDOWN_MHY N
29	LYDOWN_MHS TAT	\$1	Sleep Lying Down Persist		Y = Yes N = No	LYDOWN_MHS TAT
30	LYDOWN_MHD UR	2	Sleep Lying Down Duration			LYDOWN_MHD UR
32	RHINC_MHYN	\$1	Rhinorrhea/Co ngestion Occurrence		Y = Yes N = No U = Unknown	RHINC_MHYN
33	RHINC_MHSTA T	\$1	Rhinorrhea/Co ngestion Persist		Y = Yes N = No	RHINC_MHSTA T
34	RHINC_MH DU R	2	Rhinorrhea/Co ngestion Duration			RHINC_MH DU R

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
35	SORE_MHYN	\$1	Sore Throat Occurrence		Y = Yes N = No U = Unknown	SORE_MHYN
36	SORE_MHSTAT	\$1	Sore Throat Persist		Y = Yes N = No	SORE_MHSTAT
37	SORE_MHDUR	2	Sore Throat Duration			SORE_MHDUR
38	ANOSM_MHYN	\$1	Anosmia Occurrence		Y = Yes N = No U = Unknown	ANOSM_MHYN
39	ANOSM_MHST AT	\$1	Anosmia Persist		Y = Yes N = No	ANOSM_MHST AT
40	ANOSM_MHDU R	2	Anosmia Duration			ANOSM_MHDU R
41	AGEUS_MHYN	\$1	Ageusia Occurrence		Y = Yes N = No U = Unknown	AGEUS_MHYN
42	AGEUS_MHST AT	\$1	Ageusia Persist		Y = Yes N = No	AGEUS_MHST AT
43	AGEUS_MHDU R	2	Ageusia Duration			AGEUS_MHDU R
45	ANOREX_MHY N	\$1	Anorexia Occurrence		Y = Yes N = No U = Unknown	ANOREX_MHY N

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
46	ANOREX_MHS TAT	\$1	Anorexia Persist		Y = Yes N = No	ANOREX_MHS TAT
47	ANOREX_MHD UR	2	Anorexia Duration			ANOREX_MHD UR
48	NAUSEA_MHY N	\$1	Nausea/Vomiti ng Occurrence		Y = Yes N = No U = Unknown	NAUSEA_MHY N
49	NAUSEA_MHS TAT	\$1	Nausea/Vomiti ng Persist		Y = Yes N = No	NAUSEA_MHS TAT
50	NAUSEA_MHD UR	2	Nausea/Vomiti ng Duration			NAUSEA_MHD UR
51	DIAR_MHYN	\$1	Diarrhea Occurrence		Y = Yes N = No U = Unknown	DIAR_MHYN
52	DIAR_MHSTAT	\$1	Diarrhea Persist		Y = Yes N = No	DIAR_MHSTAT
53	DIAR_MHDUR	2	Diarrhea Duration			DIAR_MHDUR
54	ABD_MHYN	\$1	Abdominal Pain Occurrence		Y = Yes N = No U = Unknown	ABD_MHYN
55	ABD_MHSTAT	\$1	Abdominal Pain Persist		Y = Yes N = No	ABD_MHSTAT

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
56	ABD_MHDUR	2	Abdominal Pain Duration			ABD_MHDUR
58	FATIGUE_MHY N	\$1	Fatigue Occurrence		Y = Yes N = No U = Unknown	FATIGUE_MHY N
59	FATIGUE_MHS TAT	\$1	Fatigue Persist		Y = Yes N = No	FATIGUE_MHS TAT
60	FATIGUE_MHD UR	2	Fatigue Duration			FATIGUE_MHD UR
61	MYALG_MHYN	\$1	Myalgia Occurrence		Y = Yes N = No U = Unknown	MYALG_MHYN
62	MYALG_MHST AT	\$1	Myalgia Persist		Y = Yes N = No	MYALG_MHST AT
63	MYALG_MH DU R	2	Myalgia Duration			MYALG_MH DU R
64	HEAD_MHYN	\$1	Headache Occurrence		Y = Yes N = No U = Unknown	HEAD_MHYN
65	HEAD_MHSTA T	\$1	Headache Persist		Y = Yes N = No	HEAD_MHSTA T
66	HEAD_MHDUR	2	Headache Duration			HEAD_MHDUR

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: COVID-19 Symptoms

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
67	CONFUS_MHY N	\$1	Confusion Occurrence		Y = Yes N = No U = Unknown	CONFUS_MHY N
68	CONFUS_MHS TAT	\$1	Confusion Persist		Y = Yes N = No	CONFUS_MHS TAT
69	CONFUS_MHD UR	2	Confusion Duration			CONFUS_MHD UR
70	CHILL_MHYN	\$1	Chills Occurrence		Y = Yes N = No U = Unknown	CHILL_MHYN
71	CHILL_MHSTA T	\$1	Chills Persist		Y = Yes N = No	CHILL_MHSTA T
72	CHILL_MHDUR	2	Chills Duration			CHILL_MHDUR
74	SKIN_MHYN	\$1	Skin Finding Occurrence		Y = Yes N = No U = Unknown	SKIN_MHYN
75	SKIN_MHOSP	\$200	Skin Finding Specify			SKIN_MHOSP
76	SKIN_MHSTAT	\$1	Skin Finding Persist		Y = Yes N = No	SKIN_MHSTAT
77	SKIN_MHDUR	2	Skin Finding Duration			SKIN_MHDUR
79	OSP_MHYN	\$1	Other Occurrence		Y = Yes N = No	OSP_MHYN

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: COVID-19 Symptoms
Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
80	OSP_MHTERM	\$200	Other Specify			OSP_MHTERM
81	OSP_MHSTAT	\$1	Other Persist		Y = Yes N = No	OSP_MHSTAT
82	OSP_MHDUR	2	Other Duration			OSP_MHDUR
83	OSP2_MHTER M	\$200	Other 2 Specify			OSP2_MHTER M
84	OSP2_MHSTAT	\$1	Other 2 Persist		Y = Yes N = No	OSP2_MHSTAT
85	OSP2_MHDUR	2	Other 2 Duration			OSP2_MHDUR
86	OSP3_MHTER M	\$200	Other 3 Specify			OSP3_MHTER M
87	OSP3_MHSTAT	\$1	Other 3 Persist		Y = Yes N = No	OSP3_MHSTAT
88	OSP3_MHDUR	2	Other 3 Duration			OSP3_MHDUR

Treatment/Diagnostic Information

Did the participant receive supplemental oxygen?

Yes ☐ **2**
No ☐

Did the participant have pneumonia on radiologic imaging (e.g., chest x-ray or CT scan)?

Yes ☐ **3**
No ☐
Unknown ☐

Was the participant enrolled in any experimental treatment trials?

Yes ☐ **4**
No ☐

If "Yes", specify: _____

5

Did the participant receive any of the following medications?

Complete below AND record on the Concomitant Medications log, as applicable.

Remdesivir

Yes ☐ **7**
No ☐
Unknown ☐

Chloroquine/hydroxychloroquine +/- azithromycin

Yes ☐ **8**
No ☐
Unknown ☐

Tocilizumab or other IL-6 pathway inhibitors

Yes ☐ **9**
No ☐
Unknown ☐

Convalescent plasma

Yes ☐ **10**
No ☐
Unknown ☐

Corticosteroids

Yes ☐ **11**
No ☐
Unknown ☐

Hospitalization Information

Was the participant hospitalized?

Yes ☐ **13**
No ☐

If "No", end of form.

Did the participant receive intensive care?

Yes ☐ **14**
No ☐

If "Yes", was the participant intubated?

Yes ☐ **15**
No ☐

If "Yes", did the participant receive ECMO?

Yes ☐ **16**
No ☐
Unknown ☐

Was the participant discharged on supplemental oxygen?

Yes ☐ **17**
No ☐

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: COVID-19 Treatment and Hospitalization
Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	OXY_MHYN	\$1	Supplemental Oxygen		Y = Yes N = No	OXY_MHYN
3	PNEU_MHYN	\$1	Pneumonia On Imaging		Y = Yes N = No U = Unknown	PNEU_MHYN
4	TRIALS_MHYN	\$1	Experimental Treatment Trial		Y = Yes N = No	TRIALS_MHYN
5	MHOSP	\$200	Experimental Treatment Trial Specify			MHOSP
7	REMD_CMYN	\$1	Remdesivir		Y = Yes N = No U = Unknown	REMD_CMYN
8	HCQAZ_CMYN	\$1	Chloroquine Hydroxychloro quine Or Azithromycin		Y = Yes N = No U = Unknown	HCQAZ_CMYN
9	TOCILI_CMYN	\$1	Tocilizumab Or IL-6 Pathway Inhibitor		Y = Yes N = No U = Unknown	TOCILI_CMYN
10	CONVAL_CMY N	\$1	Convalescent Plasma		Y = Yes N = No U = Unknown	CONVAL_CMY N
11	CORT_CMYN	\$1	Corticosteroids		Y = Yes N = No U = Unknown	CORT_CMYN

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: COVID-19 Treatment and Hospitalization
Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13	HOSP_MHYN	\$1	Hospitalized		Y = Yes N = No	HOSP_MHYN
14	ICU_MHYN	\$1	Intensive Care		Y = Yes N = No	ICU_MHYN
15	INT_MHYN	\$1	Intubated		Y = Yes N = No	INT_MHYN
16	ECMO_MHYN	\$1	ECMO		Y = Yes N = No U = Unknown	ECMO_MHYN
17	DISOXY_MHYN	\$1	Supplemental Oxygen On Discharge		Y = Yes N = No	DISOXY_MHYN

Did the participant complete this visit?

Yes ☐ ①
No ☐

Visit date

_____ ②

Did the participant exit/terminate the study at this visit?

Yes ☐ ③
No ☐

If "Yes", complete Study Termination form.

ADDITIONAL PROCEDURES/FORMS

COVID-19 Symptoms

☐ ⑤

COVID-19 Treatment and Hospitalization

☐ ⑥

Nasal Specimen for Antibodies

☐ ⑦

Nasal Specimen for SARS-CoV-2 PCR

☐ ⑧

Participant Transfer

☐ ⑨

Participant Receipt

☐ ⑩

SARS-CoV-2 Exposure

☐ ⑪

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Date of Visit

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	SVYN	\$1	Did the participant complete this visit?		Y = Yes N = No	SVYN
2	SVSTDTC	dd MMM yyyy	Visit date			SVSTDTC
3	SUPPTER	\$1	Did the participant exit/terminate the study at this visit?		Y = Yes N = No	SUPPTER
5	MHSYMP	1	COVID-19 Symptoms			MHSYMP
6	MHTRT	1	COVID-19 Treatment and Hospitalization			MHTRT
7	BSNSAB	1	Nasal Wash Collection			BSNSAB
8	BSNSPCR	1	Nasopharyngeal/Nasal Swab			BSNSPCR
9	TRANSFER	1	Participant Transfer			TRANSFER
10	RECEIPT	1	Participant Receipt			RECEIPT
11	EXCOV2	1	SARS-CoV-2 Exposure			EXCOV2

Thank you for being a part of our research. As you know, the virus SARS-CoV-2 and the disease it can cause, COVID-19, affect many people. People live in different places, with different customs, cultures, sexual practices, and beliefs. We hope to include people from different communities in our research. We respect all people. Not all questions we ask in our research will apply to you. Because we do not want to make assumptions, we ask the same questions of everyone. We want you to be comfortable in speaking with us. You do not have to answer any question that makes you uncomfortable.

Now I am going to ask you some questions about yourself. The answers to these questions will tell us more about who you are, such as your age and race. I will also ask you about your sex and gender. Please feel free to ask any questions about things that you don't understand. All of your answers will be kept private.

Region

Americas ☐ 2
Africa (South Africa) ☐
Africa (other African countries) ☐

Date of birth.

3

Age.

Fixed Unit: yrs 4

The next question is about your sex. When I ask about your sex, I am asking about what sex you were determined to be at birth, which is generally done by looking at a baby's genitals (sex organs).

Sex assigned at birth

Male ☐ 6
Female ☐

Ethnicity.

Hispanic or Latino. ☐ 7
Not Hispanic or Latino. ☐

Race

Mark all that apply.

American Indian or Alaska Native.

☐ 9

Asian.	<input type="checkbox"/>	10
--------	--------------------------	-----------

Black or African American.	<input type="checkbox"/>	11
----------------------------	--------------------------	-----------

Native Hawaiian or other Pacific Islander.	<input type="checkbox"/>	12
--	--------------------------	-----------

White.	<input type="checkbox"/>	13
--------	--------------------------	-----------

Other.	<input type="checkbox"/>	14
--------	--------------------------	-----------

.If "Other", specify:		15
-----------------------	--	-----------

.Do you currently have health insurance/coverage or medical aid?	Yes. <input type="checkbox"/>	16
	No. <input type="checkbox"/>	
	Don't know. <input type="checkbox"/>	
	Prefer not to answer. <input type="checkbox"/>	

.If Region is "Americas", what is the highest level of formal schooling you have completed?	No formal education. <input type="checkbox"/>	17
	Did not graduate from high school. <input type="checkbox"/>	
	High school graduate or GED. <input type="checkbox"/>	
	Some college/AA degree/technical school training. <input type="checkbox"/>	
	Undergraduate college degree (BS/BA). <input type="checkbox"/>	
	Some graduate school. <input type="checkbox"/>	
	Master's degree. <input type="checkbox"/>	
	Doctorate/medical degree/law degree. <input type="checkbox"/>	
	Don't know. <input type="checkbox"/>	
	Prefer not to answer. <input type="checkbox"/>	

.If Region is "Africa (South Africa)" or "Africa (other African countries)", what is the highest level of formal schooling you have completed?

- No formal education. ☐ 18
- Some primary school. ☐
- Completed primary school. ☐
- Some secondary/high school. ☐
- Completed secondary/high school. ☐
- Some university/technical education (associates/bachelors/technical degree). ☐
- Completed university/technical education (associates/bachelors/technical degree). ☐
- National certificate/trade certificate/national diploma/occupational certificate. ☐
- Some graduate school (doctorate/masters/honours/higher education degree). ☐
- Completed graduate school (doctorate/masters/honours/higher education degree). ☐
- Prefer not to answer. ☐

.If Region is "Africa (other African countries)", end of form.

Gender.

Mark all that apply.

Gender is the social part of being male or female, and relates to your self-identity. I am asking whether you consider yourself to be transgender male, transgender female, gender queer, gender variant or gender non-conforming, female, or male or if you identify yourself in an additional category. How do you identify your gender?

Male. ☐ 21

Female. ☐ 22

Transgender Male. ☐ 23

Transgender Female. ☐ 24

Gender Nonconforming/Gender Variant. ☐ 25

Gender Queer. ☐ 26

Self-identify. ☐ 27

.If "Self-identify", specify: _____ 28

Prefer not to answer. ☐ 29

The next question asks about your sexual orientation. By sexual orientation, I mean who are you sexually attracted to.

.How do you identify your sexual orientation? Gay/Lesbian/Homosexual. ☐ 31
Bisexual. ☐
Queer. ☐
Two Spirit. ☐
Straight/Heterosexual. ☐
Additional category. ☐
Not sure. ☐
Prefer not to answer. ☐

.If "Additional category", specify: _____ 32

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Demographics

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	REGION	1	Region		1 = Americas 2 = Africa (South Africa) 3 = Africa (other African countries)	REGION
3	BIRTHDAT	dd- MMM- yyyy	Date of Birth			BIRTHDAT
4	AGE	3	Age at screening			AGE
6	SEX	\$1	Sex at Birth		M = Male F = Female	SEX
7	ETHNIC	1	Ethnicity		1 = Hispanic or Latino. 2 = Not Hispanic or Latino.	ETHNIC
9	RACEAMIND	1	American Indian or Alaska Native			RACEAMIND
10	RACEASIAN	1	Asian			RACEASIAN
11	RACEAFRAM	1	Black or African American			RACEAFRAM
12	RACEHAWAII	1	Native Hawaiian or other Pacific Islander			RACEHAWAII

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Demographics

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13	RACECAUC	1	White			RACECAUC
14	RACEOTH	1	Race Other			RACEOTH
15	RACEOSP	\$200	Race Other Specify			RACEOSP
16	MEDAID_SCOR\$2 RES		Currently Have Medical Aid		1 = Yes. 2 = No. 3 = Don't know. 4 = Prefer not to answer.	MEDAID_SCOR RES
17	EDLEVEL_SCO 2 RRES		Highest Level Formal Education		1 = No formal education. 2 = Did not graduate from high school. 3 = High school graduate or GED. 4 = Some college/AA degree/technic al school training. 5 = Undergraduate college degree (BS/BA). 6 = Some graduate school. 7 = Master's degree. 8 = Doctorate/med ical degree/law degree.	EDLEVEL_SCO RRES

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Demographics

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				9 = Don't know. 10 = Prefer not to answer.	
18 EDLEVELAF_S 2 CORRES		Highest Level Formal Education		1 = No formal education. 2 = Some primary school. 3 = Completed primary school. 4 = Some secondary/hig h school. 5 = Completed secondary/hig h school. 6 = Some university/tech nical education (associates/ba chelors/technic al degree). 7 = Completed university/tech nical education (associates/ba chelors/technic al degree). 8 = National certificate/trad e certificate/nati onal diploma/occup ational certificate.	EDLEVELAF_S CORRES

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Demographics

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				9 = Some graduate school (doctorate/ma sters/honours/ higher education degree). 10 = Completed graduate school (doctorate/ma sters/honours/ higher education degree). 11 = Prefer not to answer.	
21 GNDRM_SCOR 1 RES		Gender Male			GNDRM_SCOR RES
22 GNDERW_SCO 1 RRES		Gender Female			GNDERW_SCO RRES
23 GNDRTM_SCO 1 RRES		Gender Transgender Male			GNDRTM_SCO RRES
24 GNDRTW_SCO 1 RRES		Gender Transgender Female			GNDRTW_SCO RRES
25 GNDRGNC_SC 1 ORRES		Gender Nonconforming /Gender Variant			GNDRGNC_SC ORRES

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Demographics

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
26	GNDRGQ_SCO 1 RRES		Gender Queer			GNDRGQ_SCO RRES
27	GNDRSI_SCOR 1 RES		Gender Self-identify			GNDRSI_SCOR RES
28	GNDROSP_SC \$200 ORRES		Gender Self-identify Other Specify			GNDROSP_SC ORRES
29	GNDRNA_SCO 1 RRES		Gender Prefer not to answer			GNDRNA_SCO RRES
31	SEXORIEN_SC 1 ORRES		Sexual Orientation		1 = Gay/Lesbian/H omosexual. 2 = Bisexual. 3 = Queer. 4 = Two Spirit. 5 = Straight/Heter osexual. 6 = Additional category. 7 = Not sure. 8 = Prefer not to answer.	SEXORIEN_SC ORRES
32	SEXORIENOSP \$200 _SCORRES		Sexual Orientation Other Specify			SEXORIENOSP _SCORRES

Interim visit code

1

Date of visit

2

What is/are the reason(s) for this interim visit?

Mark all that apply.

Participant missing part or all of a scheduled study visit and is outside of visit window.

☐ 4

Participant contacted site to report updated Medical History.

☐ 5

Update Medical History log.

Repeat specimen collection

☐ 6

Other reason

☐ 7

If "Other reason", specify (max. 200 characters):

8

Did the participant exit/terminate the study at this visit?

Yes ☐ 9

If "Yes", complete Termination form.

No ☐

FORMS COMPLETED AT INTERIM VISIT:

COVID-19 Symptoms

☐ 11

COVID-19 Treatment and Hospitalization

☐ 12

Nasal Specimen for SARS-CoV-2 PCR

☐ 13

Participant Transfer ☐ 14

Participant Receipt ☐ 15

SARS-CoV-2 Exposure ☐ 16

Specimen Collection - Blood ☐ 17

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Interim Visit

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	INTVSTCDE	3.1	Interim visit code			INTVSTCDE
②	SVSTDTC1	dd MMM yyyy	Date of visit			SVSTDTC1
④	INTMSD	1	Participant missed or will miss all or part of a regularly scheduled study visit and is outside of visit window.			INTMSD
⑤	INTMH	1	Participant contacted site to report updated medical history.			INTMH
⑥	INTSPEC	1	Repeat specimen collection			INTSPEC
⑦	INTOTH	1	Other reason			INTOTH
⑧	INTOSP	\$200	If "Other reason", specify			INTOSP
⑨	SUPPTER1	\$1	Did the participant exit/terminate the study at this visit?		Y = Yes N = No	SUPPTER1

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL**Form: Interim Visit****Generated On: 22 Jun 2020 15:06:12**

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
11	MHSYMP	1	COVID-19 Symptoms			MHSYMP
12	MHTRT	1	COVID-19 Treatment and Hospitalization			MHTRT
13	BSNSPCR	1	Nasal Specimen for SARS-CoV-2 PCR			BSNSPCR
14	TRANSFER	1	Participant Transfer			TRANSFER
15	RECEIPT	1	Participant Receipt			RECEIPT
16	EXCOV2	1	SARS-CoV-2 Exposure			EXCOV2
17	BSBLD	1	Specimen Collection - Blood			BSBLD

Participant Information

Height

Fixed Unit: cm

2

Weight

Fixed Unit: kg

3

Targeted Conditions

Does the participant have any of the following conditions?

If "Yes", record details in Medical History log below and/or on Concomitant Medications log, as applicable.

Hypertension

Yes ☐

5

No ☐

COPD/emphysema/asthma

Yes ☐

6

No ☐

Congestive heart failure

Yes ☐

7

No ☐

Myocarditis/pericarditis

Yes ☐

8

No ☐

Diabetes

Yes ☐

9

No ☐

If "Yes", does the participant have renal disease, eye disease or peripheral neuropathy?

Yes ☐

10

No ☐

Record any medication use, including insulin, on the Concomitant Medications log.

Chronic kidney disease

Yes ☐ **12**
No ☐

Immune system disorders

Yes ☐ **13**
No ☐

Record any immunosuppressant medications on the Concomitant Medication log.

Has the participant ever smoked cigarettes?

Yes ☐ **15**
No ☐

If "Yes", does the participant currently smoke cigarettes?

Yes ☐ **16**
No ☐

Has the participant ever smoked marijuana?

Yes ☐ **17**
No ☐

If "Yes", does the participant currently smoke marijuana?

Yes ☐ **18**
No ☐

Medical History

Description of condition/event

20

Start date of condition/event

21

Is the condition ongoing?

Yes ☐ **22**

No ☐

Is condition/event gradable?

Yes ☐ **23**

No ☐

Severity grade

Grade 1 (Mild) ☐ **24**

Grade 2 (Moderate) ☐

Grade 3 (Severe) ☐

Grade 4 (Potentially
life-threatening) ☐

Comments (max. 450 characters):

25

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Medical History

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	HEIGHT_VSOR RES	3	Height			HEIGHT_VSOR RES
3	WEIGHT_VSO RRES	4.1	Weight			WEIGHT_VSO RRES
5	HYPER_MHYN	\$1	Hypertension		Y = Yes N = No	HYPER_MHYN
6	CEA_MHYN	\$1	COPD/Emphysema/Asthma		Y = Yes N = No	CEA_MHYN
7	CHF_MHYN	\$1	Congestive Heart Failure		Y = Yes N = No	CHF_MHYN
8	MYO_MHYN	\$1	Myocarditis/Pericarditis		Y = Yes N = No	MYO_MHYN
9	DIAB_MHYN	\$1	Diabetes		Y = Yes N = No	DIAB_MHYN
10	DIABDX_MHYN	\$1	Renal Disease/Eye Disease/Peripheral Neuropathy		Y = Yes N = No	DIABDX_MHYN
12	CKD_MHYN	\$1	Chronic Kidney Disease		Y = Yes N = No	CKD_MHYN
13	ISD_MHYN	\$1	Immune System Disorders		Y = Yes N = No	ISD_MHYN


HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Medical History

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
15	TOB_SUTRT	\$1	Cigarettes Ever		Y = Yes N = No	TOB_SUTRT
16	TOB_SUNCF	\$1	Cigarettes Current		Y = Yes N = No	TOB_SUNCF
17	MJ_SUTRT	\$1	Marijuana Ever		Y = Yes N = No	MJ_SUTRT
18	MJ_SUNCF	\$1	Marijuana Current		Y = Yes N = No	MJ_SUNCF
20	MHTERM	\$200	Medical History Event Reported Term			MHTERM
21	MHSTDAT	dd- MMM- yyyy	Start Date of Medical History Event			MHSTDAT
22	MHONGO	\$1	Medical History Event Ongoing		Y = Yes N = No	MHONGO
23	MHYN_SEV	\$1	Medical History Event Gradable		Y = Yes N = No	MHYN_SEV
24	MHSEV	1	Medical History Event Severity/Inten sity		1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	MHSEV

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: Medical History
Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
 COVAL	\$450	Comments			COVAL

Use this form to document nasal wash/swab collection for antibody testing.

Was specimen collected?

Yes ☐ 2
No ☐

If "No", end of form.

Specimen collection date

4

Specimen collection time

5

Specimen collection location

Clinical research site ☐ 6
Elsewhere (e.g. Home) ☐

If "Clinic", was the procedure performed by participant or by clinic staff?

Participant ☐ 7
Clinic staff ☐

Specimen collection type

Nasal Wash ☐ 8
Nasal Swab ☐

Were all requirements of the specimen collection met per the SSP?

Yes ☐ 9
No ☐

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

Comments (max. 600 characters):

11

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Nasal Specimen for Antibodies

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	BSYN	\$1	Any Specimen Collected		Y = Yes N = No	BSYN
4	BSDAT	dd MMM yyyy	Specimen Collection Date			BSDAT
5	BSTIM	HH:nn	Specimen Collection Time			BSTIM
6	BSLOC	1	Specimen Collection Location		1 = Clinical research site 2 = Elsewhere (e.g. Home)	BSLOC
7	BSMETHOD	1	Procedure Performed By Participant Or By Clinic Staff?		1 = Participant 2 = Clinic staff	BSMETHOD
8	BSANTREGAB	1	Specimen Collection Type		1 = Nasal Wash 2 = Nasal Swab	BSANTREGAB
9	BSCOND	\$1	Specimen Collection Requirements Met?		Y = Yes N = No	BSCOND
11	BSCOVAL	\$600	Comments			BSCOVAL

Use this form to document nasopharyngeal/nasal swab collection for RT-PCR testing.

Was specimen collected?

Yes ☐ 2
No ☐

If "No", end of form.

Specimen collection date

4

Specimen collection time

5

Specimen collection location

Clinical research site ☐ 6
Elsewhere (e.g. Home) ☐

If "Clinic", was the procedure performed by participant or by clinic staff?

Participant ☐ 7
Clinic staff ☐

Swab type

Nasopharyngeal ☐ 8
Nasal ☐

Were all requirements of the specimen collection met per the SSP?

Yes ☐ 9
No ☐

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

Comments (max. 600 characters):

11

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Nasal Specimen for SARS-CoV-2 PCR

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	BSYN	\$1	Any Specimen Collected		Y = Yes N = No	BSYN
4	BSDAT	dd MMM yyyy	Specimen Collection Date			BSDAT
5	BSTIM	HH:nn	Specimen Collection Time			BSTIM
6	BSLOC	1	Specimen Collection Location		1 = Clinical research site 2 = Elsewhere (e.g. Home)	BSLOC
7	BSMETHOD	1	Procedure Performed By Participant Or By Clinic Staff?		1 = Participant 2 = Clinic staff	BSMETHOD
8	BSANTREGPCR	1	Swab Type		1 = Nasopharyngeal 2 = Nasal	BSANTREGPCR
9	BSCOND	\$1	Specimen Collection Requirements Met?		Y = Yes N = No	BSCOND
11	BSCOVAL	\$600	Comments			BSCOVAL

Participant ID:		1
NOW		2

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: Participant Identifier
Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	SUBJID	\$9	Subject Identifier			SUBJID
②	SUBJID_NOW	dd MMM yyyy HH nn				SUBJID_NOW

Name of receiving study site

- Atlanta - Hope Clinic ☒ 1
- Atlanta - Ponce de Leon Center ☐
- Baltimore - Johns Hopkins University ☐
- Birmingham - Alabama ☐
- Boston - Brigham and Women's Hospital Vaccine ☐
- Boston - Fenway Health ☐
- Chapel Hill ☐
- Chicago - AYAR at CORE ☐
- Cleveland - Case ☐
- Los Angeles - UCLA CARE Center ☐
- Nashville - Vanderbilt Vaccine ☐
- New Orleans - Adolescent Trials Unit ☐
- New York - Bronx Prevention Center ☐
- New York - Harlem Prevention Center ☐
- New York - NY Blood Center ☐
- New York - Physicians & Surgeons ☐
- Newark - New Jersey Medical School ☐
- Philadelphia - Penn Prevention ☐
- Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection ☐
- San Francisco - Bridge HIV ☐
- Seattle Vaccine Trials Unit ☐
- Washington, DC - George Washington University ☐
- Iquitos - Asociacion Civil Selva Amazonica ☐
- Lima - Barranco ☐
- Lima - San Marcos/CITBM ☐
- Lima - San Miguel ☐
- Lima - Via Libre ☐
- Bloemfontein ☐
- Cape Town - Emavundleni ☐
- Cape Town - Groote Schuur ☐

-
- Cape Town - Khayelitsha ☐
- Durban - Botha's Hill ☐
- Durban - Chatsworth ☐
- Durban - eThekweni ☐
- Durban - Isipingo ☐
- Durban - Tongaat ☐
- Durban - Verulam ☐
- Harare - Seke South ☐
- Harare - St. Mary's ☐
- Harare - Zengeza ☐
- Klerksdorp ☐
- Ladysmith ☐
- Lilongwe - Malawai ☐
- Lusaka - Matero ☐
- Lusaka - ZHERP ☐
- Mamelodi ☐
- Maputo ☐
- Masiphumelele ☐
- Mbeya ☐
- Mthatha ☐
- Ndola ☐
- Rustenburg ☐
- Soshanguve ☐
- Soweto - Bara ☐
- Soweto - Kliptown ☐
- Tembisa - Clinic 3 ☐
- Tembisa - Clinic 4 ☐
- Vulindlela ☐

Name of transferring study site

- Atlanta - Hope Clinic ☐ 2
- Atlanta - Ponce de Leon Center ☐

-
- Baltimore - Johns Hopkins University ☐
 - Birmingham - Alabama ☐
 - Boston - Brigham and Women's Hospital Vaccine ☐
 - Boston - Fenway Health ☐
 - Chapel Hill ☐
 - Chicago - AYAR at CORE ☐
 - Cleveland - Case ☐
 - Los Angeles - UCLA CARE Center ☐
 - Nashville - Vanderbilt Vaccine ☐
 - New Orleans - Adolescent Trials Unit ☐
 - New York - Bronx Prevention Center ☐
 - New York - Harlem Prevention Center ☐
 - New York - NY Blood Center ☐
 - New York - Physicians & Surgeons ☐
 - Newark - New Jersey Medical School ☐
 - Philadelphia - Penn Prevention ☐
 - Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection ☐
 - San Francisco - Bridge HIV ☐
 - Seattle Vaccine Trials Unit ☐
 - Washington, DC - George Washington University ☐
 - Iquitos - Asociacion Civil Selva Amazonica ☐
 - Lima - Barranco ☐
 - Lima - San Marcos/CITBM ☐
 - Lima - San Miguel ☐
 - Lima - Via Libre ☐
 - Bloemfontein ☐
 - Cape Town - Emavundleni ☐
 - Cape Town - Groote Schuur ☐
 - Cape Town - Khayelitsha ☐
 - Durban - Botha's Hill ☐
-

-
- Durban - Chatsworth ☐
 - Durban - eThekweni ☐
 - Durban - Isipingo ☐
 - Durban - Tongaat ☐
 - Durban - Verulam ☐
 - Harare - Seke South ☐
 - Harare - St. Mary's ☐
 - Harare - Zengeza ☐
 - Klerksdorp ☐
 - Ladysmith ☐
 - Lilongwe - Malawai ☐
 - Lusaka - Matero ☐
 - Lusaka - ZHERP ☐
 - Mamelodi ☐
 - Maputo ☐
 - Masiphumelele ☐
 - Mbeya ☐
 - Mthatha ☐
 - Ndola ☐
 - Rustenburg ☐
 - Soshanguve ☐
 - Soweto - Bara ☐
 - Soweto - Kliptown ☐
 - Tembisa - Clinic 3 ☐
 - Tembisa - Clinic 4 ☐
 - Vulindlela ☐

Date informed consent signed at receiving site

3

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① RECSITENM	3	Name of receiving study site		787 = Atlanta - Hope Clinic 709 = Atlanta - Ponce de Leon Center 700 = Baltimore - Johns Hopkins University 821 = Birmingham - Alabama 726 = Boston - Brigham and Women's Hospital Vaccine 819 = Boston - Fenway Health 706 = Chapel Hill 844 = Chicago - AYAR at CORE 704 = Cleveland - Case 701 = Los Angeles - UCLA CARE Center 783 = Nashville - Vanderbilt Vaccine 855 = New Orleans - Adolescent Trials Unit 734 = New York - Bronx Prevention Center 745 = New York - Harlem Prevention Center	RECSITENM

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				825 = New York - NY Blood Center 777 = New York - Physicians & Surgeons 820 = Newark - New Jersey Medical School 863 = Philadelphia - Penn Prevention 793 = Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection 764 = San Francisco - Bridge HIV 778 = Seattle Vaccine Trials Unit 801 = Washington, DC - George Washington University 732 = Iquitos - Asociacion Civil Selva Amazonica 714 = Lima - Barranco 848 = Lima - San Marcos/CITBM 715 = Lima - San Miguel 831 = Lima - Via Libre 868 = Bloemfontein	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				779 = Cape Town - Emavundleni 816 = Cape Town - Groote Schoor 835 = Cape Town - Khayelitsha 789 = Durban - Botha's Hill 761 = Durban - Chatsworth 785 = Durban - eThekweni 803 = Durban - Isipingo 807 = Durban - Tongaat 548 = Durban - Verulam 754 = Harare - Seke South 762 = Harare - St. Mary's 774 = Harare - Zengeza 775 = Klerksdorp 832 = Ladysmith 720 = Lilongwe - Malawai 751 = Lusaka - Matero 865 = Lusaka - ZHERP 870 = Mamelodi 823 = Maputo 869 = Masiphumelele 824 = Mbeya 836 = Mthatha 866 = Ndola 814 = Rustenburg	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				829 = Soshanguve 782 = Soweto - Bara 834 = Soweto - Kliptown 830 = Tembisa - Clinic 3 874 = Tembisa - Clinic 4 790 = Vulindlela	
② TRNSFSITENM 3		Name of transferring study site		787 = Atlanta - Hope Clinic 709 = Atlanta - Ponce de Leon Center 700 = Baltimore - Johns Hopkins University 821 = Birmingham - Alabama 726 = Boston - Brigham and Women's Hospital Vaccine 819 = Boston - Fenway Health 706 = Chapel Hill 844 = Chicago - AYAR at CORE 704 = Cleveland - Case 701 = Los Angeles - UCLA CARE Center	TRNSFSITENM

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				783 = Nashville - Vanderbilt Vaccine 855 = New Orleans - Adolescent Trials Unit 734 = New York - Bronx Prevention Center 745 = New York - Harlem Prevention Center 825 = New York - NY Blood Center 777 = New York - Physicians & Surgeons 820 = Newark - New Jersey Medical School 863 = Philadelphia - Penn Prevention 793 = Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection 764 = San Francisco - Bridge HIV 778 = Seattle Vaccine Trials Unit 801 = Washington, DC - George Washington University	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				732 = Iquitos - Asociacion Civil Selva Amazonica 714 = Lima - Barranco 848 = Lima - San Marcos/CITBM 715 = Lima - San Miguel 831 = Lima - Via Libre 868 = Bloemfontein 779 = Cape Town - Emavundleni 816 = Cape Town - Groote Schoor 835 = Cape Town - Khayelitsha 789 = Durban - Botha's Hill 761 = Durban - Chatsworth 785 = Durban - eThekweni 803 = Durban - Isipingo 807 = Durban - Tongaat 548 = Durban - Verulam 754 = Harare - Seke South 762 = Harare - St. Mary's 774 = Harare - Zengeza 775 = Klerksdorp 832 = Ladysmith	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Receipt

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				720 = Lilongwe - Malawai 751 = Lusaka - Matero 865 = Lusaka - ZHERP 870 = Mamelodi 823 = Maputo 869 = Masiphumelele 824 = Mbeya 836 = Mthatha 866 = Ndola 814 = Rustenburg 829 = Soshanguve 782 = Soweto - Bara 834 = Soweto - Kliptown 830 = Tembisa - Clinic 3 874 = Tembisa - Clinic 4 790 = Vulindlela	
3 RECICDAT	dd MMM yyyy	Date informed consent signed at receiving site			RECICDAT

Name of transferring study site

- Atlanta - Hope Clinic ☒ 1
- Atlanta - Ponce de Leon Center ☐
- Baltimore - Johns Hopkins University ☐
- Birmingham - Alabama ☐
- Boston - Brigham and Women's Hospital Vaccine ☐
- Boston - Fenway Health ☐
- Chapel Hill ☐
- Chicago - AYAR at CORE ☐
- Cleveland - Case ☐
- Los Angeles - UCLA CARE Center ☐
- Nashville - Vanderbilt Vaccine ☐
- New Orleans - Adolescent Trials Unit ☐
- New York - Bronx Prevention Center ☐
- New York - Harlem Prevention Center ☐
- New York - NY Blood Center ☐
- New York - Physicians & Surgeons ☐
- Newark - New Jersey Medical School ☐
- Philadelphia - Penn Prevention ☐
- Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection ☐
- San Francisco - Bridge HIV ☐
- Seattle Vaccine Trials Unit ☐
- Washington, DC - George Washington University ☐
- Iquitos - Asociacion Civil Selva Amazonica ☐
- Lima - Barranco ☐
- Lima - San Marcos/CITBM ☐
- Lima - San Miguel ☐
- Lima - Via Libre ☐
- Bloemfontein ☐
- Cape Town - Emavundleni ☐
- Cape Town - Groote Schuur ☐

Cape Town - Khayelitsha ☐

Durban - Botha's Hill ☐

Durban - Chatsworth ☐

Durban - eThekweni ☐

Durban - Isipingo ☐

Durban - Tongaat ☐

Durban - Verulam ☐

Harare - Seke South ☐

Harare - St. Mary's ☐

Harare - Zengeza ☐

Klerksdorp ☐

Ladysmith ☐

Lilongwe - Malawai ☐

Lusaka - Matero ☐

Lusaka - ZHERP ☐

Mamelodi ☐

Maputo ☐

Masiphumelele ☐

Mbeya ☐

Mthatha ☐

Ndola ☐

Rustenburg ☐

Soshanguve ☐

Soweto - Bara ☐

Soweto - Kliptown ☐

Tembisa - Clinic 3 ☐

Tembisa - Clinic 4 ☐

Vulindlela ☐

Name of receiving study site

Atlanta - Hope Clinic ☐ 2

Atlanta - Ponce de Leon Center ☐

-
- Baltimore - Johns Hopkins University ☐
 - Birmingham - Alabama ☐
 - Boston - Brigham and Women's Hospital Vaccine ☐
 - Boston - Fenway Health ☐
 - Chapel Hill ☐
 - Chicago - AYAR at CORE ☐
 - Cleveland - Case ☐
 - Los Angeles - UCLA CARE Center ☐
 - Nashville - Vanderbilt Vaccine ☐
 - New Orleans - Adolescent Trials Unit ☐
 - New York - Bronx Prevention Center ☐
 - New York - Harlem Prevention Center ☐
 - New York - NY Blood Center ☐
 - New York - Physicians & Surgeons ☐
 - Newark - New Jersey Medical School ☐
 - Philadelphia - Penn Prevention ☐
 - Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection ☐
 - San Francisco - Bridge HIV ☐
 - Seattle Vaccine Trials Unit ☐
 - Washington, DC - George Washington University ☐
 - Iquitos - Asociacion Civil Selva Amazonica ☐
 - Lima - Barranco ☐
 - Lima - San Marcos/CITBM ☐
 - Lima - San Miguel ☐
 - Lima - Via Libre ☐
 - Bloemfontein ☐
 - Cape Town - Emavundleni ☐
 - Cape Town - Groote Schuur ☐
 - Cape Town - Khayelitsha ☐
 - Durban - Botha's Hill ☐
-

-
- Durban - Chatsworth ☐
 - Durban - eThekweni ☐
 - Durban - Isipingo ☐
 - Durban - Tongaat ☐
 - Durban - Verulam ☐
 - Harare - Seke South ☐
 - Harare - St. Mary's ☐
 - Harare - Zengeza ☐
 - Klerksdorp ☐
 - Ladysmith ☐
 - Lilongwe - Malawai ☐
 - Lusaka - Matero ☐
 - Lusaka - ZHERP ☐
 - Mamelodi ☐
 - Maputo ☐
 - Masiphumelele ☐
 - Mbeya ☐
 - Mthatha ☐
 - Ndola ☐
 - Rustenburg ☐
 - Soshanguve ☐
 - Soweto - Bara ☐
 - Soweto - Kliptown ☐
 - Tembisa - Clinic 3 ☐
 - Tembisa - Clinic 4 ☐
 - Vulindlela ☐

Visit of last completed contact with participant

- V1.0 - Enrollment ☒ 3
 - V2.0 - Follow-up ☐
 - V3.0 - Follow-up ☐
 - V4.0 - Follow-up ☐
 - Interim Visit ☐
-

If "Interim visit", specify Interim visit code	<div></div>	4
Date participant's records were sent to receiving study site	<div></div>	5

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① TRNSFSITENM 3		Name of transferring study site		787 = Atlanta - Hope Clinic 709 = Atlanta - Ponce de Leon Center 700 = Baltimore - Johns Hopkins University 821 = Birmingham - Alabama 726 = Boston - Brigham and Women's Hospital Vaccine 819 = Boston - Fenway Health 706 = Chapel Hill 844 = Chicago - AYAR at CORE 704 = Cleveland - Case 701 = Los Angeles - UCLA CARE Center 783 = Nashville - Vanderbilt Vaccine 855 = New Orleans - Adolescent Trials Unit 734 = New York - Bronx Prevention Center 745 = New York - Harlem Prevention Center	TRNSFSITENM

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				825 = New York - NY Blood Center 777 = New York - Physicians & Surgeons 820 = Newark - New Jersey Medical School 863 = Philadelphia - Penn Prevention 793 = Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection 764 = San Francisco - Bridge HIV 778 = Seattle Vaccine Trials Unit 801 = Washington, DC - George Washington University 732 = Iquitos - Asociacion Civil Selva Amazonica 714 = Lima - Barranco 848 = Lima - San Marcos/CITBM 715 = Lima - San Miguel 831 = Lima - Via Libre 868 = Bloemfontein	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				779 = Cape Town - Emavundleni 816 = Cape Town - Groote Schoor 835 = Cape Town - Khayelitsha 789 = Durban - Botha's Hill 761 = Durban - Chatsworth 785 = Durban - eThekweni 803 = Durban - Isipingo 807 = Durban - Tongaat 548 = Durban - Verulam 754 = Harare - Seke South 762 = Harare - St. Mary's 774 = Harare - Zengeza 775 = Klerksdorp 832 = Ladysmith 720 = Lilongwe - Malawai 751 = Lusaka - Matero 865 = Lusaka - ZHERP 870 = Mamelodi 823 = Maputo 869 = Masiphumelele 824 = Mbeya 836 = Mthatha 866 = Ndola 814 = Rustenburg	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				829 = Soshanguve 782 = Soweto - Bara 834 = Soweto - Kliptown 830 = Tembisa - Clinic 3 874 = Tembisa - Clinic 4 790 = Vulindlela	
② RECSITENM	3	Name of receiving study site		787 = Atlanta - Hope Clinic 709 = Atlanta - Ponce de Leon Center 700 = Baltimore - Johns Hopkins University 821 = Birmingham - Alabama 726 = Boston - Brigham and Women's Hospital Vaccine 819 = Boston - Fenway Health 706 = Chapel Hill 844 = Chicago - AYAR at CORE 704 = Cleveland - Case 701 = Los Angeles - UCLA CARE Center	RECSITENM

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				783 = Nashville - Vanderbilt Vaccine 855 = New Orleans - Adolescent Trials Unit 734 = New York - Bronx Prevention Center 745 = New York - Harlem Prevention Center 825 = New York - NY Blood Center 777 = New York - Physicians & Surgeons 820 = Newark - New Jersey Medical School 863 = Philadelphia - Penn Prevention 793 = Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection 764 = San Francisco - Bridge HIV 778 = Seattle Vaccine Trials Unit 801 = Washington, DC - George Washington University	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				732 = Iquitos - Asociacion Civil Selva Amazonica 714 = Lima - Barranco 848 = Lima - San Marcos/CITBM 715 = Lima - San Miguel 831 = Lima - Via Libre 868 = Bloemfontein 779 = Cape Town - Emavundleni 816 = Cape Town - Groote Schoor 835 = Cape Town - Khayelitsha 789 = Durban - Botha's Hill 761 = Durban - Chatsworth 785 = Durban - eThekweni 803 = Durban - Isipingo 807 = Durban - Tongaat 548 = Durban - Verulam 754 = Harare - Seke South 762 = Harare - St. Mary's 774 = Harare - Zengeza 775 = Klerksdorp 832 = Ladysmith	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Participant Transfer

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				720 = Lilongwe - Malawai 751 = Lusaka - Matero 865 = Lusaka - ZHERP 870 = Mamelodi 823 = Maputo 869 = Masiphumelele 824 = Mbeya 836 = Mthatha 866 = Ndola 814 = Rustenburg 829 = Soshanguve 782 = Soweto - Bara 834 = Soweto - Kliptown 830 = Tembisa - Clinic 3 874 = Tembisa - Clinic 4 790 = Vulindlela	
3 TRNSFVISIT	3	Visit code of last completed contact with participant		1 = V1.0 - Enrollment 2 = V2.0 - Follow-up 3 = V3.0 - Follow-up 4 = V4.0 - Follow-up 98 = Interim Visit	TRNSFVISIT
4 INTERIMCD	5.1	Interim Visit Code			INTERIMCD

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: Participant Transfer
Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
5 RECRDSNTDAT	dd MMM yyyy	Date participant's records were sent to receiving study site			RECRDSNTDAT

Household Exposure

At the time of, or just before, their positive SARS-CoV-2 test, did the participant live with any other individuals in their household?

Yes ☐ **2**
No ☐

If "Yes", please provide the below information for all individuals in the participant's household

Age

Fixed Unit: yrs **4**

Did the person have confirmed SARS-CoV-2 infection by a laboratory test?

Yes ☐ **5**
No ☐

If "Yes", was the laboratory test performed prior to the study participant's symptoms or test results?

Yes ☐ **6**
No ☐

Did the person develop symptoms consistent with COVID-19?

Yes ☐ **7**
No ☐

If "Yes", did the symptoms develop before the study participant's symptoms or test results?

Yes ☐ **8**
No ☐

Other Exposure

What is the participant's OSHA risk of occupational exposure?

Lower exposure risk ☐ **10**
Medium exposure risk ☐
High exposure risk ☐
Very high exposure risk ☐
Not applicable ☐

Does the participant have regular exposure to young children (<5 years old)?

Yes ☐ **11**
No ☐

Did the participant have exposure to any other individuals with confirmed SARS-CoV-2 infection or COVID-19 outside the home setting?

Yes ☐ **12**
No ☐

If "No", end of form.

Date of last contact with individual

13

Exposure description (max. 200 characters):

14

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: SARS-CoV-2 Exposure

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	AP_DMYN	\$1	Any Other Individuals In Participant Household		Y = Yes N = No	AP_DMYN
4	AP_AGE	3	Age			AP_AGE
5	APCOVID_LBY N	\$1	Confirmed SARS-CoV-2 Infection		Y = Yes N = No	APCOVID_LBY N
6	APCOVID_LBP REYN	\$1	Lab Test Before Participants Symptoms/Res ults		Y = Yes N = No	APCOVID_LBP REYN
7	APSYMP_MHY N	\$1	COVID-19 Symptoms		Y = Yes N = No	APSYMP_MHY N
8	APSYMP_MHPR EYN	\$1	Symptoms Before Participant Symptoms/Res ults		Y = Yes N = No	APSYMP_MHPR EYN
10	OSHA_ERSCAT	\$2	OSHA Risk Of Occupational Exposure		1 = Lower exposure risk 2 = Medium exposure risk 3 = High exposure risk 4 = Very high exposure risk NA = Not applicable	OSHA_ERSCAT

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: SARS-CoV-2 Exposure

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
11	EXPCH_DMYN	\$1	Regular Exposure To Young Children		Y = Yes N = No	EXPCH_DMYN
12	EXPOTH_DMY N	\$1	Exposure To Confirmed SARS-CoV-2 or COVID-19 Outside Home		Y = Yes N = No	EXPOTH_DMY N
13	EXPOTH_DAT	dd- MMM yyyy	Date Of Last Contact			EXPOTH_DAT
14	EXPOTH_DES	\$200	Exposure Description			EXPOTH_DES

Approximate date of test _____ ①

Test result
Detected ☐ ②
Not Detected ☐
Indeterminate ☐

Where was the specimen collection done?
Inpatient ☐ ③
Outpatient ☐
Employer ☐
Urgent Care ☐
Emergency Room ☐
Home ☐
Other ☐

If "Other", specify: _____ ④

Test type
RT-PCR ☐ ⑤
Antibody/serology ☐
Other ☐

If "Other", specify: _____ ⑥

Specimen collection type
Nasal or Nasopharyngeal Swab ☐ ⑦
Nasal Wash ☐
Oropharyngeal Swab ☐
Saliva ☐
Blood ☐
Other ☐

If "Other", specify: _____ ⑧

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: SARS-CoV-2 Test Results

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	LBDAT	dd- MMM yyyy	Approximate Test Date			LBDAT
2	LBORRES	1	Test Result		1 = Detected 2 = Not Detected 3 = Indeterminate	LBORRES
3	LBLOC	1	Specimen Collection Location		1 = Inpatient 2 = Outpatient 3 = Employer 4 = Urgent Care 5 = Emergency Room 7 = Home 6 = Other	LBLOC
4	LBLOCOSP	\$100	Test Location Other Specify			LBLOCOSP
5	LBSPEC	1	Test Type		1 = RT-PCR 2 = Antibody/serol ogy 3 = Other	LBSPEC
6	LBSPECOSP	\$100	Test Type Other Specify			LBSPECOSP
7	LBANTREG	1	Specimen Collection Type		1 = Nasal or Nasopharyngeal Swab 2 = Nasal Wash 3 = Oropharyngeal Swab	LBANTREG

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: SARS-CoV-2 Test Results

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				4 = Saliva 5 = Blood 6 = Other	
8 LBANTREGOSP \$100		Specimen Collection Type Other Specify			LBANTREGOSP

Informed consent date _____ **1**

Is the participant eligible to enroll in the study? Yes ☐ **2**
If "No", go to "Eligibility status". No ☐

Group ☐ **3**
Group 1 - not previously hospitalized, without specific clinical spectrums or outcomes
Group 2 - previously hospitalized, without specific clinical spectrums or outcomes ☐
Group 3 - with specific clinical spectrums or outcomes ☐

If "Group 3", specify: ☐ **4**
Recovered after intubation
Prolonged viral shedding ☐
Myocarditis/pericarditis ☐
Rapid recovery from COVID-19 ☐
Second positive SARS-CoV-2 RT-PCR test result after a negative result ☐
Other ☐

If "Other", specify: (max. 200 characters) _____ **5**

Eligibility status ☐ **6**
Eligible and enrolled
Ineligible ☐
Incomplete Screening ☐

If "Ineligible", select reason(s) why participant is ineligible. ☐ **7**
Inclusion Criterion 1 - Age 18 or older.
Inclusion Criterion 2 - Reports having had a positive test for SARS-CoV-2. ☐

Inclusion Criterion 3 - Reports resolution of COVID-19 within 1-8 weeks of enrollment OR, if asymptomatic infection, reports positive SARS-CoV-2 test within 2-10 weeks of enrollment. ☐

Inclusion Criterion 4 - Access to a participating HVTN or HPTN CRS and willingness to be followed for the planned duration of the study. ☐

Inclusion Criterion 5 - Ability and willingness to provide informed consent. ☐

Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study. ☐

Inclusion Criterion 7 - Volunteers who were assigned female sex at birth: negative urine or serum beta human chorionic gonadotropin (β -HCG) pregnancy test within 4 days of enrollment visit (ie, prior to enrollment blood draw or nasal collections). ☐

Exclusion Criterion 1 - Reports current COVID-19. ☐

Exclusion Criterion 2 - Pregnant. ☐

Exclusion Criterion 3 - Receipt of SARS-CoV-2 specific antibodies (eg, convalescent plasma or sera, monoclonal antibodies, hyperimmune globulin). ☐

Exclusion Criterion 4 - SARS-CoV-2 vaccine(s) received in a prior vaccine trial. ☐

Exclusion Criterion 5 - Any medical, psychiatric, occupational, or other condition that, in the judgment of the investigator, would interfere with, or serve as a contraindication to, protocol adherence or a volunteer's ability to give informed consent. ☐

Volunteer inappropriate for enrollment in the judgement of the investigator. ☐

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Screening Outcome

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	RFICDAT	dd MMM yyyy	Informed Consent Date			RFICDAT
②	IEENRYN	\$1	Is Ppt Eligible to Enroll in Study		Y = Yes N = No	IEENRYN
③	IEGRP	1	Group		1 = Group 1 - IEGRP not previously hospitalized, without specific clinical spectrums or outcomes 2 = Group 2 - previously hospitalized, without specific clinical spectrums or outcomes 3 = Group 3 - with specific clinical spectrums or outcomes	
④	OSP_IEGRP3	1	Group 3 Specify		1 = Recovered OSP_IEGRP3 after intubation 2 = Prolonged viral shedding 3 = Myocarditis/pe ricarditis 4 = Rapid recovery from COVID-19 5 = Second positive SARS-CoV-2 RT-PCR test result after a negative result	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Screening Outcome

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
6 = Other					
⑤ OSP_IEGRP	\$200	Group 3 Other Specify			OSP_IEGRP
⑥ IESTATUS	1	Eligibility Status		1 = Eligible and enrolled 3 = Ineligible 4 = Incomplete Screening	IESTATUS
⑦ IETEST	2	Inclusion Exclusion Criterion Result		1 = Inclusion Criterion 1 - Age 18 or older. 2 = Inclusion Criterion 2 - Reports having had a positive test for SARS-CoV-2. 3 = Inclusion Criterion 3 - Reports resolution of COVID-19 within 1-8 weeks of enrollment OR, if asymptomatic infection, reports positive SARS-CoV-2 test within 2-10 weeks of enrollment.	IETEST

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Screening Outcome

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				<p>4 = Inclusion Criterion 4 - Access to a participating HVTN or HPTN CRS and willingness to be followed for the planned duration of the study.</p> <p>5 = Inclusion Criterion 5 - Ability and willingness to provide informed consent.</p> <p>6 = Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study.</p> <p>7 = Inclusion Criterion 7 - Volunteers who were assigned female sex at birth: negative urine or serum beta human chorionic gonadotropin (β-HCG) pregnancy test within 4 days of enrollment visit (ie, prior to enrollment blood draw or nasal collections).</p>	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Screening Outcome

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
------------	-----------	-----------	-------	--------	----------------------

8 = Exclusion
Criterion 1 -
Reports
current
COVID-19.
9 = Exclusion
Criterion 2 -
Pregnant.
12 = Exclusion
Criterion 3 -
Receipt of
SARS-CoV-2
specific
antibodies (eg,
convalescent
plasma or
sera,
monoclonal
antibodies,
hyperimmune
globulin).
13 = Exclusion
Criterion 4 -
SARS-CoV-2
vaccine(s)
received in a
prior vaccine
trial.

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Screening Outcome

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				10 = Exclusion Criterion 5 - Any medical, psychiatric, occupational, or other condition that, in the judgment of the investigator, would interfere with, or serve as a contraindicatio n to, protocol adherence or a volunteer's ability to give informed consent. 11 = Volunteer inappropriate for enrollment in the judgement of the investigator.	

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL
Form: Specimen Collection - Blood
Generated On: 22 Jun 2020 15:06:12

Do NOT use this form for any local lab specimens. Use this form ONLY to document the collection of blood specimens that will be sent to the site processing lab.

Was specimen collected?

Yes ☐ **2**
No ☐

If "No", end of form.

Specimen collection date

4

Specimen collection time

5

EDTA

Collected ☐ **6**
Not collected ☐

ACD

Collected ☐ **7**
Not collected ☐

SST

Collected ☐ **8**
Not collected ☐

SST - Clinical SARS-CoV-2 IgG Antibody Results

Collected ☐ **9**
Not collected ☐

Mark if a new Specimen Collection form is needed to complete specimen collection requirements for this visit.

☐ **10**

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Specimen Collection - Blood

Generated On: 22 Jun 2020 15:06:12

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	BSYN	\$1	Any Specimen Collected		Y = Yes N = No	BSYN
4	BSDAT	dd MMM yyyy	Specimen Collection Date			BSDAT
5	BSTIM	HH:nn	Specimen Collection Time			BSTIM
6	BSEDTA	1	EDTA Collected/Not Collected		1 = Collected 2 = Not collected	BSEDTA
7	BSACD	1	ACD Collected/Not Collected		1 = Collected 2 = Not collected	BSACD
8	BSSST	1	SST Collected/Not Collected		1 = Collected 2 = Not collected	BSSST
9	BSSSTAB	1	Antibody Results Collected/Not Collected		1 = Collected 2 = Not collected	BSSSTAB
10	ADDSPPE	1	Add Specimen Collection Form			ADDSPPE

Date of study exit

1

Primary reason for completion/discontinuation

Scheduled exit visit/end of study

2

Death

Participant refused further participation

Participant is unwilling or unable to comply with required study procedures

Investigator decision

Unable to contact participant

Early study closure

Protocol deviation

Pregnancy

Study terminated by sponsor

Participant unable to adhere to visit schedule

Participant relocated, no follow-up planned

Other, specify

If "Other", specify (max. 200 characters):

3

If "Death", enter date of death.

4

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	DSSTDAT	dd MMM yyyy	Date of Study Completion or Discontinuation			DSSTDAT
②	DSTERM	2	Study Completion Reported Term		1 = Scheduled exit visit/end of study 2 = Death 3 = Participant refused further participation 4 = Participant is unwilling or unable to comply with required study procedures 6 = Investigator decision 8 = Unable to contact participant 10 = Early study closure 11 = Protocol deviation 13 = Pregnancy 15 = Study terminated by sponsor 17 = Participant unable to adhere to visit schedule 18 = Participant relocated, no follow-up planned	DSTERM

HVTN405_HPTN1901_Version_1.4_AUX_BK_19JUN2020: ALL

Form: Study Termination

Generated On: 22 Jun 2020 15:06:12

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				99 = Other, specify	
③ DSTERMOSP	\$200	Study Completion Reported Term Other Specify			DSTERMOSP
④ DTHDAT	dd MMM yyyy	Date of Death			DTHDAT